UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,437	12/20/1999	ISA ODIDI	10914-11	7273

7590 06/04/2003

DINSMORE & SHOHL
255 EAST FIFTH STREET
1900 CHEMED CENTER
CINCINNATI, OH 45202

EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	29

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/833,622	Applicant(s) ISHII ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Continued Examination, received by the Office March 18, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, and 5-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,000,962 to Sangekar *et al.*, in view of US 5,162,117 to Stupak *et al.* and further in view of US Patent 6,083,532 to Zhang *et al.*.

.Sangekar *et al.* teach a long acting formulation which comprises a swellable polymer. More specifically, Sangekar *et al.* teach that examples of swellable hydrophilic polymers include HPMC, HPC, HMC, HEC, and HPC (c 2, l 57-61). Furthermore, Sangekar *et al.* teach the presence of a binder in the composition to combine with the swellable hydrophilic polymer, such as ethylcellulose (c 3, l 51-55). The reference also teaches that the binder be present at between 2-6% of the weight of the composition (c 3, l 58). The reference also teaches the inclusion of additional excipients, such as diluents (spray dried lactose) and lubricants (c 3, l 41-50).

Therefore, the teachings of Sangekar *et al.* teach the the use of polymers, such as HPMC and HEC, in combination with EC, for the creation of a long acting pharmaceutical formulation.

Sangekar *et al.* do not specifically teach how long the formulation will release. However, the reference does teach that the formulation is suitable for once daily or twice daily administration. This implies that the dosage form releases for either 12 or 24 hours, before a new dosage form is necessary (c 2, l 32).

Sangekar *et al.* do not specifically teach the use of HPMC and HEC together, in combination with EC.

Zhang *et al.* disclose a sustained release drug formulation. More specifically, Zhang *et al.* disclose a tablet for sustained release of a drug comprising an effective amount of a drug to be released at a controlled rate and a sustained release formulation comprising different types of polymers, wherein the pH independent gelling polymer comprises at least one of a hydroxypropyl methyl cellulose, a hydroxypropyl ethyl cellulose, a hydroxypropyl cellulose, a hydroxyethyl cellulose... (columns 4-5, claim 2). This disclosure suggests that hydroxypropyl methyl cellulose and hydroxyethyl cellulose are known to be used in tablet formulations, in combination.

Sangekar *et al.* do not teach the specific additives and excipient as claimed by applicant.

Stupak *et al.* is relied upon for the teaching that applicant's claimed excipients are all very well known in the pharmaceutical art, and therefore would have been obvious to include in any pharmaceutical formulation, especially one which has the same function of controlled release. Stupak *et al.* disclose a controlled release solid dosage tablet. More specifically, Stupak *et al.* teach that the tablet core of their invention can include excipients including diluents such as

microcrystalline cellulose, lubricants, glidants such as silicon dioxide, as well as sodium lauryl sulfate and lactose (c 2-3). Additionally, Stupak *et al.* teach that their composition can have a coating, which can be a methacrylic acid copolymer coating (c 5, claim 5). Again, the Stupak reference is relied upon to show that applicant's claimed excipients are all known in the art of pharmaceutical formulations, and therefore would be obvious to include in a tablet formulation.

It is the position of the examiner that the main component of applicant's invention is the mixture of polymers in the core of the composition, which is suggested by the above combination of Sangekar *et al.* in view of Zhang *et al.*. Sangekar *et al.* teach the use of swellable polymers, such as HEC and HPMC, in combination with EC as a binder. Zhang *et al.* teach that HEC, HPMC, and other similar polymers are known to be used in combination with one another. One skilled in the art would recognize that each of these polymers, and their interactions and equivalences, are well known in the art. Further, one of ordinary skill in the art would have been motivated to combine the teachings of Sangekar *et al.* and Zhang *et al.*. with Stupak *et al.*, and use any of the well known pharmaceutical excipients described by Stupak *et al.* in the composition suggested by Sangekar *et al.* in view of Zhang *et al.*. The expected result would be a successful controlled release pharmaceutical composition. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. E. Pulliam
Patent Examiner
Art Unit 1615
May 28, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600